

## **REMARKS**

After entry of this Request for Reconsideration, the pending claims are: claims 1, 2, 4, 5, 9, 10 and 15-21, which are the same claims that were pending prior to entry of the present Request for Reconsideration. The Office Action dated February 2, 2009 has been carefully considered. Claims 3, 6-8 and 11-14 were previously canceled. Reconsideration and allowance of the present application in view of the following Remarks is respectfully requested.

In the Office Action dated February 2, 2009, the Examiner:

- rejected claims 1, 2, 4, 5, 9 and 18 under 35 U.S.C. 103(a) as being unpatentable over U.S. Published Patent Application No. 2001/0012937 to Schaffler-Wachter (“Schaffler-Wachter”) in view of U.S. Patent No. 2,877,918 to Gardner (“Gardner”) further in view of U.S. Patent No 5,989,254 to Katz (“Katz”);
- rejected claims 1, 2, 4, 5, 10 and 18 under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter in view of U.S. Patent No. 2,877,918 to Gardner further in view of U.S. Patent No 6,090,111 to Nichols (“Nichols”);
- rejected claims 15 and 19-21 under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter in view of Gardner; and
- rejected claims 16 and 17 under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter in view of Gardner further in view of Katz.

### **INDEPENDENT CLAIM 1**

Independent claim 1 and claims 2, 4, 5, 9 and 18, which depend therefrom, have been rejected as being unpatentable over Schaffler-Wachter in view of Gardner further in view of Katz. In addition,

independent claim 1 and claims 2, 4, 5, 10 and 18, which depend therefrom, have been rejected as being unpatentable over Schaffler-Wachter in view of Gardner further in view of Nichols.

Independent claim 1 is directed to a device for connecting a longitudinal carrier to a bone screw and recites as follows:

a connection element ... a sealing cap ... and a set screw threadably coupled to [a] rear end of the sealing cap for securing the position of the longitudinal carrier inserted in [a] first channel; wherein [an] external surface of the connection element and [an] internal surface of the ... sealing cap include complementary non-threaded bulges and depressions for securing the sealing cap to the connection element, the bulges and depressions providing a plurality of discrete axial latch positions parallel to the central axis, each successive latch position axially displacing the sealing cap over the connection element, the bulges and depressions extending continuously, concentrically, and non-threadingly around the central axis on the connection element external surface and the sealing cap internal surface, the concentric continuity of the bulges and depressions interrupted by .. first and second channels ...

The Examiner agrees that Schaffler-Wachter does not disclose, teach or suggest complementary non-threaded bulges and depressions for securing a sealing cap to a connection element wherein the bulges and depressions provide a plurality of discrete axial latch positions such that each successive latch position axially displaces the sealing cap over the connection element, as recited by independent claim 1. Instead the Examiner relies upon Gardner to disclose non-threaded bulges and depressions for providing a plurality of discrete axial latch positions. The Examiner asserts that combining the non-threaded bulges and depressions of Gardner with the sealing cap and connection device of Schaffler-Wachter would be obvious to one of ordinary skill in the art. Applicant respectfully disagrees with the Examiner's assertion.

Referring to Figs. 1 and 2, Gardner is directed to a sealable bottle cap 10 that interacts with a bottle neck 12 formed on a bottle. The bottle cap 10 and bottle neck 12 are made from a distortable plastic material. The bottle cap 10 is moveable from a closed position (as shown in Fig. 2) to an open position (as shown in Fig. 1). In the closed position, the bottle cap 10 is sealed with respect to the bottle neck 12 so that fluid is prevented from leaking. In the opened position, the bottle cap 10 is spaced from the bottle neck 12 so that fluid is permitted to escape from the cap 10. More specifically, the bottle cap 10 includes two stop members 24, 26 for engaging a ring 14 formed on the bottle neck 12. Stop member 24 is located distally of stop member 26. In the closed position, stop member 26 engages the ring 14 such that the top of the bottle neck 12 is sealed by a skirt 30 formed at the proximal end of the bottle cap 10 so that any fluid contained in the bottle is prevented from leaking. In the open position, stop member 24 engages the ring 14 such that the top of the bottle cap 10 is spaced from the top of the bottle neck 12 so that fluid contained in the bottle can flow out of the cap 10.

Applicant respectfully disagrees that one having ordinary skill in the art would modify the polyaxial pedicle screw disclosed in Schaffler-Wachter in view of the bottle snap cap disclosed in Gardner to construct a device for connecting a longitudinal carrier to a bone screw wherein complementary non-threaded bulges and depressions are formed on a sealing cap and a connection element in order to connect the longitudinal carrier to the bone screw, as is claimed in claim 1 of the present application.

Gardner is directed to a sealable bottle cap 10 for coacting with a bottle neck 12 formed on a bottle container. The bottle cap 10 and bottle neck 12 being made from “a distortable plastic material, to the end that [the bottle cap 10] can be pressed onto the neck of the bottle.” *See* Gardner col. 2, lns. 37-

40. As such, the disclosure of Gardner is unrelated to the field of medical devices and in particular is unrelated to spinal fixation devices. “To rely on a reference under 35 U.S.C. 103, it must be analogous prior art.” *See* MPEP 2141.01(a). “[A] reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, *logically would have commended itself to an inventor's attention* in considering his or her invention as a whole.” *See KSR International co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1397 (2007) (*emphasis added*). Applicants respectfully submit that one having ordinary skill in the art of designing medical implants would not logically commend themselves to bottle snap cap references, such as Gardner, when designing the device for connecting a longitudinal carrier to a bone screw, as is claimed in the present application. Accordingly, Applicants respectfully submit that Gardner is not analogous prior art and may not be properly combined with the pedicle screw disclosed in Schaffler-Wachter.

Furthermore, Gardner is directed to the design of a reusable, sealable bottle cap designed to satisfy several conditions. In particular, the bottle cap “must provide for the easy manual operation of the same; it must seal the contents of the bottle against leakage when in the closed position; and it must discharge only out of the discharge opening when it is in use.” *See* Gardner, col. 2, lns. 51-56. In contrast, Applicant is concerned with designing an implant for spinal fixation, and specifically an implant for securing the position of a longitudinal carrier with respect to a bone screw in a patient's body. The device claimed in claim 1 is designed to minimize space requirements and to be implanted via a reduced number of surgical instruments and steps. The Applicant is not concerned with providing a sealable cap nor is the device of claim 1 in any way sealable as it contains various bores, channels, slots, openings, *etc.* for receiving and securing the position of the longitudinal carrier. Accordingly, it is

respectfully submitted that one of ordinary skill in the art would not look to a plastic, sealable bottle cap as taught by Gardner in designing a device for spinal fixation, and particularly for an implant for securing the position of a longitudinal carrier with respect to a bone screw.

The field in which the Gardner reference resides, sealable bottle caps, is so remote from the claimed subject matter that it could not be considered reasonably pertinent and would not have logically commended itself to Applicant's attention in considering the claimed invention as a whole. MPEP 2141(a). Section I. Accordingly, a sealable bottle cap is not relevant to the invention of claim 1 and thus Gardner should be considered non-analogous art with respect thereto. As such, Applicant respectfully submits that the use of the Gardner reference was improper as it is non-analogous art. Applicant respectfully submits that the combination of Gardner with Schaffler-Wachter is improper and the 35 U.S.C. 103 rejections should be withdrawn. Allowance of independent claim 1 is respectfully requested.

Furthermore, it is respectfully submitted that the Examiner has not identified any reason why a person of ordinary skill in the art would combine Gardner with Schaffler-Wachter other than it would teach all of the elements of independent claim 1. (*See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_\_\_ (2007) "[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently known, in the prior art ... important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.") Rather, according to the Examiner, it would be obvious to one of ordinary skill in the art to incorporate the complementary bulges and depressions of the resealable container bottle of Gardner with the spinal

implant of Schaffler-Wachter even though the Examiner has not found such a device in the field of spinal fixation. A field that includes hundreds of issued patents and published applications.

It is respectfully submitted that the Applicant through his own effort and expense derived the device as claimed in independent claim 1. It is respectfully submitted that without the benefit of the Applicant's disclosure, it would not be obvious for one of ordinary skill in the art to redesign the device of Schaffler-Wachter to include complementary non-threaded bulges and depressions for securing the cap to the connection element wherein the bulges and depressions provide a plurality of discrete axial latch positions such that each successive latch position axially displaces the sealing cap over the connection element.

At best, Gardner explicitly teaches away from the combination, in that, the purpose of the stop members and ring described in Gardner is to provide a sealable cap that "must seal the contents of the bottle against leakage when in the closed position, and it must discharge only out of the discharge opening when it is use." *See* Gardner col. 2, lns. 51-56. Gardner discloses a container made of distortable plastic material. *See* Gardner col 2, lns. 37-38. Not only are these materials not suitable for use in the body, but the cap of independent claim 1 requires a cavity for receiving the connection element and a second channel extending transversely to the central axis and opening towards the front end of the sealing cap. The cavity and channel, if integrated into Gardner, destroy the entire purpose (*i.e.*, providing a sealable cap) of using bulges and depressions. *See Tec Air, Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353 (Fed. Cir. 1999) "[t]here is no suggestion to combine ... if a reference teaches away from its combination with another source ... 'A reference may be said to teach

away when a person of ordinary skill, upon reading of the reference ... would be lead in a direction divergent from the path that was taken by the applicant.’”

In addition, it is respectfully submitted, that the Examiner has in this rejection and throughout the prosecution of the present application, undertook impermissible hindsight reconstruction. It is improper hindsight reconstruction to use the Applicant’s disclosure as a blueprint to pick and choose among the individual elements of assorted prior art references in order to combine the references in a way to achieve the Applicant’s claimed invention. *Grain Processing Corp. v. American Maitze-Products Corp.*, 840 F.2d 902 (Fed. Cir. 1988).

Moreover, it is respectfully submitted that neither Katz nor Nichols overcome the short comings of Schaffler-Wachter and Gardner. Both Katz and Nichols were cited for the proposition that it would be obvious to incorporate a securing element to prevent the bone screw from passing through the upper end of the connection element. Without addressing the merits of these references and/or their combination with Schaffler-Wachter and Gardner, it is respectfully submitted that, for at least the above-identified reasons, neither Schaffler-Wachter, Gardner, Katz nor Nichols, either alone or in combination, disclose, teach or suggest non-threaded bulges and depressions for securing a sealing cap to a connection element in order to secure a longitudinal carrier to a bone screw.

Accordingly, it is respectfully submitted that independent claim 1 is allowable over Schaffler-Wachter, Gardner, Katz and Nichols, either alone or in combination. Withdrawal of these rejections and allowance of independent claim 1 is respectfully requested.

Furthermore, as claims 2, 4, 5, 9, 10 and 18 all depend from independent claim 1, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2, 4, 5, 9, 10 and 18 is also respectfully requested.

## **INDEPENDENT CLAIMS 19 AND 21**

Independent claim 19 and claim 20, which depends from claim 19, have been rejected as being unpatentable over Schaffler-Wachter in view of Gardner. Similarly, independent claim 21 and claim 15, which depends from claim 20, have been rejected as being unpatentable over Schaffler-Wachter in view of Gardner. Dependent claims 16 and 17, which depend from claim 21, have been rejected as being unpatentable over Schaffler-Wachter in view of Gardner further in view of Katz.

Independent claim 19 is directed to a device for connecting a longitudinal carrier to a bone screw, and recites, *inter alia*, as follows: a connection element, a sealing cap wherein an external surface of the connection element has a plurality of bulges formed thereon and an internal surface of the sealing cap has a plurality of depressions formed therein, complementary to the plurality of bulges, the sealing cap engages the connection element such that each of the plurality of bulges of the connection element is operative to snap-fit into at least one of the plurality of depressions of the sealing cap, the bulges and depressions providing a plurality of discrete axial latch positions parallel to the central axis, each successive latch position axially displacing the sealing cap relative to the connection element.

Similarly, independent claim 21 is directed to a device for connecting a longitudinal carrier to a bone screw, and recites, *inter alia*, as follows: a connection element and a sealing cap wherein an external surface of the connection element and an internal surface of the sealing cap include at least first



and second bulges and at least first and second complementary depressions for securing the sealing cap to the connection element, the bulges and depressions provide at least first and second axial positions of the sealing cap relative to the connection element, the first and second positions are axially displaced from one another and the sealing cap is placed in the first position by displacing the sealing cap over the connection element such that a first bulge engages a first depression, the cap being movable from the first position to the second position by further displacing the sealing cap axially so that the first bulge engages a second depression and a second bulge engages the first depression.

Thus, for reasons similar to those described above in connection with independent claim 1, it is respectfully submitted that neither Schaffler-Wachter and Gardner, whether alone or in combination, disclose, teach or suggest all of the limitations of independent claims 19 and 21. Thus, it is respectfully submitted that independent claims 19 and 21 are allowable over Schaffler-Wachter and Gardner. Withdrawal of these rejections and allowance of independent claims 19 and 21 is respectfully requested.

Furthermore, as dependent claim 20 depends from independent claim 19, and as claims 15-17 depend from independent claim 21, it is submitted that claims 15-17 and 20 are equally allowable. Withdrawal of these rejections and allowance of claims 15-17 and 20 is also respectfully requested.

With respect to claims 16 and 17 which were rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter in view of Gardner in further view of Katz, it is respectfully submitted that Katz does not overcome the short comings of Schaffler-Wachter and Gardner. Katz was cited for the proposition that it would be obvious to incorporate a securing element to prevent the bone screw from passing through the upper end of the connection element. Without addressing the merits of

this argument and/or the combination, it is respectfully submitted that, for at least the above-identified reasons, neither Schaffler-Wachter, Gardner, nor Katz, either alone or in combination, disclose, teach or suggest all of the limitations of dependent claims 16 and 17 and, specifically, the above-listed features of claim 21. Thus, it is respectfully submitted that dependent claims 16 and 17 are allowable over Schaffler-Wachter, Gardner and Katz. Withdrawal of this rejection and allowance of dependent claims 16 and 17 is respectfully requested.

## CONCLUSION

Based upon the above-listed Request for Reconsideration and remarks, Applicants respectfully submit that the present application, including claims 1, 2, 4, 5, 9, 10 and 15-21, is in condition for allowance and such action is respectfully requested.

No fee is believed due for this submission. If, however, the Commissioner determines otherwise, the Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicant's attorney at the number listed below.

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Respectfully submitted,

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